APPENDIX

PENDING CLAIMS

1. A system for averting undesirable pharmacokinetic drug interaction between a drug and concomitant drug(s), which comprises controlling the *in vivo* release time and/or release site of the drug and/or the concomitant drug(s).

2. A system for averting undesirable drug interaction between a drug and concomitant drug(s), both of which use the same route in terms of *in vivo* drug absorption, distribution, metabolism or excretion in humans, which comprises controlling the *in vivo* release time and/or release site of the drug and/or the concomitant drug(s).

3. A system for averting undesirable drug interaction between a drug and concomitant drug(s), both of which are metabolized by the same molecular species of drug-metabolizing enzyme in humans, or between a drug and concomitant drug(s) that is metabolized by the molecular species of drug-metabolizing enzymes that is inhibited by the said drug, which comprises timed-release control of the said drug or control of the site of release of the said drug to the digestive tract.

4. A system for averting undesirable drug interaction between a drug and concomitant drug(s), both of which metabolized by the drug metabolizing enzyme CYP3A4, or between a drug that inhibits CYP3A4 and concomitant drug(s) that is metabolized by CYP3A4, which comprises timed-release control of the said drug or controlling release specifically in the lower digestive tract of the said drug.

5. A drug preparation for averting undesirable pharmacokinetic drug interaction between a drug and concomitant drug(s), which comprises controlling the *in vivo* release time and/or release site of the said drug.

6. A drug preparation for averting undesirable drug interaction between a drug and concomitant drug(s), both of which use the same route in terms of *in vivo* drug absorption, distribution, metabolism or excretion in humans, which comprises controlling the *in vivo* release time and/or release site of the said drug.

7. A drug preparation for averting undesirable drug interaction on the *in vivo* kinetics of a drug by concomitant drug(s) that inhibits *in vivo* metabolism of the said drug in humans, which comprises timed-release control of the concomitant drug or control of the site of release of the concomitant drug to the digestive tract.

8. A drug preparation for averting undesirable effects on the blood concentration of a drug by concomitant drug(s) that inhibits the *in vivo* metabolism of the said drug by CYP3A4 in humans, which comprises timed release control of the said drug or controlling release specifically in the lower digestive tract of the concomitant drug.

9. The drug preparation according to Claim 8, whereby the said drug and the concomitant drug are a combination selected from anfentanyl, fentanyl, sulfentanyl, cocaine, dihydrocodeine, oxycodeine, tramadol, erythromycin, clarithromycin, troleandomycin, azithromycin, itraconazole, ketoconazole, dapsone, midazolam, triazolam, alprazolam, diazepam, zolpidem, felodipine, nifedipine, nitrendipine, amlodipine, isradipine, nicardipine, nimodipine, nisoldipine, nildipine, bepridil, diltiazem, verapamil, astemizole, terfenadine, loratidine, cyclosporine, tacrolimus, rapamycin, amiodarone, disopyramide, lidocaine, propafenone, quinidine, imipramine, amitriptyline, clomipramine, nafazodone, sertraline, trazodone, haloperidol, pimozide, carbamazepine, ethosuximide, trimethadione, simvastatin, lovastatin, fluvastatin, atrovastatin, etoposide, ifosfamide, paclitaxel, tamoxifen, taxol, vinblastine, vincristine, indinavir, ritonavir, saquinavir, testosterone, prednisolone, methylprednisolone,

dexamethasone, proguanil, warfarin, finasteride, flutamide, ondansteron, zatsetrone, cisapride, cortisol, zonisamide, desmethyldiazepam, and conivaptan.

10. A method for averting undesirable pharmacokinetic drug interaction between a drug and concomitant drug(s), comprising administering to patients a drug preparation with which the *in vivo* release time and/or release site of the said drug is controlled.

11. A method for averting undesirable drug-interaction between a drug and concomitant drug, both of which use the same route in terms of *in vivo* drug absorption, distribution, metabolism or excretion in humans, comprising administering to patients a drug preparation with which the *in vivo* release time and/or release site of the said drug is controllable.

12. A method for averting undesirable drug-interaction on the *in vivo* kinetics of a drug by concomitant drug that inhibits the *in vivo* metabolism of the said drug by drug-metabolizing enzymes in humans, comprising administering to patients a drug preparation with which timed-release of the concomitant drug or release site of the concomitant drug to the digestive tract is controllable.

13. A method for averting undesirable effects on the blood concentration of a drug by concomitant drug that inhibits the *in vivo* metabolism of the said drug by CYP3A4, comprising administering to patients a drug preparation with which timed-release of the concomitant drug or release of the concomitant drug specifically to the lower digestive tract is controllable.

14. The method according to Claim 13, whereby the said drug and the concomitant drug are a combination selected from anfentanyl, fentanyl, sulfentanyl, cocaine, dihydrocodeine, oxycodeine, tramadol, erythromycin, clarithromycin, troleandomycin, azithromycin, itraconazole, ketoconazole, dapsone, midazolam, triazolam, alprazolam, diazepam,

zolpidem, felodipine, nifedipine, nitrendipine, amlodipine, isradipine, nicardipine, nimodipine, nisoldipine, nildipine, bepridil, diltiazem, verapamil, astemizole, terfenadine, loratidine, cyclosporine, tacrolimus, rapamycin, amiodarone, disopyramide, lidocaine, propafenone, quinidine, imipramine, amitriptyline, clomipramine, nafazodone, sertraline, trazodone, haloperidol, pimozide, carbamazepine, ethosuximide, trimethadione, simvastatin, lovastatin, fluvastatin, atrovastatin, etoposide, ifosfamide, paclitaxel, tamoxifen, taxol, vinblastine, vincristine, indinavir, ritonavir, saquinavir, testosterone, prednisolone, methylprednisolone, dexamethasone, proguanil, warfarin, finasteride, flutamide, ondansteron, zatsetrone, cisapride, cortisol, zonisamide, desmethyldiazepam, and conivaptan.

15. A system for averting undesirable pharmacokinetic interaction between a drug and food(s), which comprises controlling the *in vivo* release time and/or release site of the drug.

16. (New) A drug preparation for averting undesirable effects on the blood concentration of a drug by concomitant drug(s) that inhibits the *in vivo* metabolism of the said drug by CYP3A4 in humans, which comprises timed release control of the said drug or controlling release specifically in the lower digestive tract of the concomitant drug, whereby:

the said drug and the concomitant drug are a combination selected from anfentanyl, fentanyl, sulfentanyl, cocaine, dihydrocodeine, oxycodeine, tramadol, erythromycin, clarithromycin, troleandomycin, azithromycin, itraconazole, ketoconazole, dapsone, midazolam, triazolam, alprazolam, diazepam, zolpidem, felodipine, nifedipine, nitrendipine, amlodipine, isradipine, nicardipine, nimodipine, nisoldipine, nildipine, bepridil, diltiazem, verapamil, astemizole, terfenadine, loratidine, cyclosporine, tacrolimus, rapamycin, amiodarone, disopyramide, lidocaine, propafenone, quinidine, imipramine, amitriptyline, clomipramine, nafazodone, sertraline, trazodone, haloperidol, pimozide, carbamazepine, ethosuximide, trimethadione, simvastatin, lovastatin, fluvastatin, atrovastatin, etoposide, ifosfamide, paclitaxel, tamoxifen, taxol, vinblastine, vincristine, indinavir, ritonavir, saquinavir, testosterone,

prednisolone, methylprednisolone, dexamethasone, proguanil, warfarin, finasteride, flutamide, ondansteron, zatsetrone, cisapride, cortisol, zonisamide, desmethyldiazepam, and conivaptan.

17. (New) A drug preparation for averting undesirable drug interaction on the *in vivo* kinetics of a drug by concomitant drug(s) that inhibits *in vivo* metabolism of the said drug in humans, which comprises timed-release control of the concomitant drug or control of the site of release of the concomitant drug to the digestive tract whereby:

the said drug and the concomitant drug are a combination selected from anfentanyl, fentanyl, sulfentanyl, cocaine, dihydrocodeine, oxycodeine, tramadol, erythromycin, clarithromycin, troleandomycin, azithromycin, itraconazole, ketoconazole, dapsone, midazolam, triazolam, alprazolam, diazepam, zolpidem, felodipine, nifedipine, nitrendipine, amlodipine, isradipine, nicardipine, nimodipine, nisoldipine, nildipine, bepridil, diltiazem, verapamil, astemizole, terfenadine, loratidine, cyclosporine, tacrolimus, rapamycin, amiodarone, disopyramide, lidocaine, propafenone, quinidine, imipramine, amitriptyline, clomipramine, nafazodone, sertraline, trazodone, haloperidol, pimozide, carbamazepine, ethosuximide, trimethadione, simvastatin, lovastatin, fluvastatin, atrovastatin, etoposide, ifosfamide, paclitaxel, tamoxifen, taxol, vinblastine, vincristine, indinavir, ritonavir, saquinavir, testosterone, prednisolone, methylprednisolone, dexamethasone, proguanil, warfarin, finasteride, flutamide, ondansteron, zatsetrone, cisapride, cortisol, zonisamide, desmethyldiazepam, and conivaptan.